

Defendants.

No. 2:06-cv-1797

Defendants.

No. 2:06-cv-1833

Defendants.

No. 2:06-cv-2768

Defendant.

No. 2:08-cv-2141

**Goldberg, J.****March 29, 2010****MEMORANDUM OPINION**

Currently pending are Defendants' motions to dismiss the antitrust complaints filed by numerous parties.<sup>1</sup> The issue raised in these motions is whether Plaintiffs have pled sufficient antitrust allegations pursuant to the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2, to survive Defendants' motions to dismiss. The answer to this question necessitates a somewhat protracted review of divergent precedent regarding the appropriate framework to apply in analyzing what is commonly referred to as a "reverse payment settlement." These settlements are typically entered into as a result of patent litigation between a brand name drug manufacturer and generic drug manufacturers. The multi-party antitrust litigation before the Court stems from four (4) such reverse payment settlements consummated in late 2005 and early 2006, regarding the drug Provigil®.<sup>2</sup> The agreements at issue were between the pharmaceutical company Cephalon, Inc., and several generic drug manufacturers

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<sup>1</sup> The specific motions at issue are: "Defendant Cephalon, Inc.'s Motion to Dismiss the Direct Purchasers' First Consolidated Amended Complaint and the Rite Aid Complaint," (doc. no. 200); "Generic Defendants' Motion to Dismiss the Amended Complaints of the Direct Purchaser Plaintiffs and End Payor Plaintiffs," (doc. no. 201); "Defendant Cephalon, Inc.'s Motion to Dismiss the Walgreen Complaint," (doc. no. 211); and "The Generic Defendants' Motion to Dismiss the Complaint Filed by Walgreen Co., et al.," (doc. no. 216), in King Drug Co. of Florence, Inc., et al. v. Cephalon, Inc., et al., 2:06-cv-1797.

"Defendant Cephalon, Inc.'s Motion to Dismiss the Amended Consolidated Class Action Complaint of End Payors and the Amended Complaint of Avmed, Inc.," (doc. no. 86); and "Generic Defendants' Motion to Dismiss the Amended Complaints of the Direct Purchaser Plaintiffs and End Payor Plaintiffs," (doc. no. 87) in Vista Healthplan, Inc., et al. v. Cephalon, Inc., et al., 2:06-cv-1833.

"Defendant Cephalon, Inc.'s Motion to Dismiss Counts III Through XIII of the Amended Complaint and to Strike Prayers for Relief," (doc. no. 157); and "Generic Defendants' Motion to Dismiss Apotex's First Amended Complaint," (doc. no. 158), in Apotex, Inc. v. Cephalon, Inc., et al., 2:06-cv-2768.

"Defendant Cephalon, Inc.'s Motion to Dismiss the First Amended Complaint," (doc. no. 43) in Fed. Trade Comm'n v. Cephalon, Inc., 2:08-cv-2141.

<sup>2</sup> These settlements were reached in the case of Cephalon, Inc. v. Mylan Pharms., Inc., et al., No. 2:03-cv-1394 (D.N.J.).

(hereinafter “the Generic Defendants”), all of whom are Defendants in the cases before this Court. Plaintiffs generally allege that these agreements constitute an unlawful restraint of trade. For the reasons detailed below, except for selected counts brought under several state statutes, Defendants’ motions will be denied.

## **I. BACKGROUND**

### **A. Structure of the Litigation and Parties**

Sixteen (16) separate cases, many of which are class actions, commenced as a result of the patent litigation settlements noted above. These cases are now collectively referred to as the In re Modafinil litigation and were consolidated into four (4) subcategories pursuant to FED. R. CIV. P. 42(a). These subcategories are: The King Drug Direct Purchaser Class Action; The Vista Healthplan End Payor Class Action; The Apotex Litigation; and The F.T.C. Litigation. A brief description of the Plaintiffs in each of the four (4) cases is as follows:

All direct purchaser proposed class action cases were consolidated into King Drug Co. of Florence, Inc., et al. v. Cephalon, Inc., et al., 2:06-cv-1797.<sup>3</sup> The Plaintiffs in these cases are companies who directly purchased Provigil® from Cephalon for re-distribution. The end payor proposed class action cases were consolidated into Vista Healthplan, Inc., et al. v. Cephalon, Inc.,

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<sup>3</sup> Rochester Drug Co-Operative, Inc. v. Cephalon, Inc., et al., 2:06-cv-1868; Meijer, Inc., et al. v. Cephalon, Inc., et al., 2:06-cv-1911; Burlington Drug Co., Inc. v. Cephalon, Inc., et al., 2:06-cv-2052; J. M. Smith Corp. v. Cephalon, Inc., et al., 2:06-cv-2146; SAJ Distribs., Inc., et al. v. Cephalon, Inc., 2:06-cv-3450; Rite Aid Corp., et al. v. Cephalon, Inc., et al., 2:09-cv-3820 (opt out); and Walgreen Co., et al. v. Cephalon, Inc., et al., 2:09-cv-3956 (opt out).

et al., 2:06-cv-1833.<sup>4</sup> This group of Plaintiffs includes individuals who indirectly purchased Provigil® and companies who paid for those purchases. The third case involves a generic drug manufacturer, Apotex, who has raised non-infringement and patent invalidity allegations, as well as antitrust claims in Apotex, Inc. v. Cephalon, Inc., et al., 2:06-cv-2768.<sup>5</sup> Finally, the Federal Trade Commission (hereinafter “F.T.C.”) has brought Sherman Act claims in Fed. Trade Comm’n v. Cephalon, Inc., 2:08-cv-2141.

The Defendants in each of these cases are the parties who entered into four (4) reverse settlement agreements: Cephalon and the Generic Defendants - Barr Laboratories, Inc.; Mylan Laboratories, Inc.; Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc.; and Ranbaxy Laboratories, Ltd., and Ranbaxy Pharmaceuticals, Inc.

#### **B. Procedural History - In re Modafinil Litigation**

The In re Modafinil litigation commenced when The King Direct Purchaser Class Action was filed on April 27, 2006, in the Eastern District of Pennsylvania. The Vista Healthplan End Payor Class Action was filed three (3) days later on May 1, 2006, followed by The Apotex Litigation on June 26, 2006. Nine (9) other related cases were filed later in 2006 and 2007. The F.T.C. Litigation was filed on February 13, 2008, in the United States District Court for the District of Columbia and subsequently transferred to this Court on April 28, 2008.<sup>6</sup>

On April 28, 2009, all of the cases referenced above were re-assigned to the undersigned.

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<sup>4</sup> Pa. Tpk. Comm’n v. Cephalon, Inc., et al., 2:06-cv-2020; Langan v. Cephalon, Inc., et al., 2:06-cv-2507; Pa. Employees Benefit Trust Fund v. Cephalon, Inc., et al., 2:06-cv-2883; and Avmed, Inc. v. Cephalon, Inc., et al., 2:07-cv-3793 (opt out).

<sup>5</sup> Consolidated with Apotex, Inc. v. Cephalon, Inc., 2:09-cv-2416.

<sup>6</sup> Fed. Trade Comm’n v. Cephalon, Inc., 551 F.Supp.2d 21 (D.D.C. 2008).

At that time, eighteen (18) separate motions were pending, including the motions to dismiss at issue, which were denied without prejudice. The filing of amended consolidated complaints then followed as did Cephalon and the Generic Defendants' filing of consolidated motions to dismiss which are currently before the Court.<sup>7</sup>

### **C. The Drug at Issue**

The U.S. Food and Drug Administration (hereinafter "FDA") approved Cephalon's New Drug Application (hereinafter "NDA") No. 20-717 for Provigil® on December 24, 1998. Provigil® is a prescription drug used to promote wakefulness in adults with sleep disorders such as shift work disorder, obstructive sleep apnea and narcolepsy. Modafinil, the main pharmacological component of Provigil®, is a psychostimulant that enhances wakefulness and vigilance. Modafinil is an acetamide that is prescribed in 100 mg and 200 mg tablets and has the efficacy and side effects similar to amphetamines and methylphenidates (e.g., Ritalin®), but those drugs are not reasonably interchangeable with Provigil®. Cephalon's sales of Provigil® exceeded \$420 million in 2004, \$500 million in 2005, \$690 million in 2006, \$800 million in 2007, and \$920 million in 2008. (See Apotex Second Am. Compl., ¶¶ 20, 39-40, 75.)

### **D. Statutory and Regulatory Framework - The Hatch-Waxman Act**

The circuit court cases that are reviewed later in this Opinion provide an extensive analysis of the statutory and regulatory framework of the Hatch-Waxman Act. Consequently, we will not re-plow the same ground here, but rather summarize portions of the Act that are pertinent to the issues

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<sup>7</sup> On February 23, 2010, after bifurcation of Apotex's patent invalidity/non-infringement and antitrust claims, the Court denied "Defendant Cephalon, Inc.'s Motion to Dismiss Counts III Through XIII of the Amended Complaint and to Strike Prayers for Relief," as it related to counts III-V. These counts included the bifurcated patent claims. Apotex, Inc. v. Cephalon, Inc., 2010 WL 678104 (E.D.Pa. Feb. 23, 2010).

currently before the Court.

Typically, through the submission of a NDA a pharmaceutical company must obtain approval from the FDA to market a prescription drug. This application details all safety and efficacy studies, the components in the drug, the methods used in “the manufacture, process and packaging” of the drug, and any patents issued on the composition or methods of using the drug. 21 U.S.C. § 355(b)(1). The FDA publishes the patent information in the “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the “Orange Book.” See FDA Electronic Orange Book (Jan. 2010), <http://www.fda.gov/cder/ob/>.

Prior to 1984, a generic drug company also had to undertake its own costly studies regarding the efficacy and safety of a drug and file its own NDA. See Schering-Plough Corp. v. Fed. Trade Comm’n, 402 F.3d 1056, 1058-59 n. 2 (11th Cir. 2005). However, in 1984, Congress enacted the Drug Price Competition & Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, Pub.L. No. 98-417, 98 Stat. 1585 (codified at various sections of Titles 21 and 35 of the United States Code). Among its key provisions, the Hatch-Waxman Act created the Abbreviated New Drug Application process (hereinafter “ANDA”), which allows a generic drug application to piggyback on safety and efficacy studies conducted for the pioneer drug. See generally 21 U.S.C. § 355(j).

Under the Hatch-Waxman Act, the pharmaceutical company is still required to file a NDA with full-scale safety and efficacy studies listing the patents that generics might infringe in the future. Id. at § 355(b)(1). However, the Hatch-Waxman Act was designed to allow generic companies to bypass the studies required under a NDA and file an ANDA, which requires only that generic companies prove that the new drug is the bioequivalent of a brand name drug on the market. Id. at § 355(j)(2)(A). An ANDA filer must, thereafter, select one (1) of the following

certifications: (1) that the “patent information has not been filed” on the generic’s brand name equivalent (a Paragraph I certification); (2) that a patent on the branded drug has expired (a Paragraph II certification); (3) that a brand name patent exists, including “the date on which such patent will expire,” with a promise not to market until that date (a Paragraph III certification); or (4) “that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted” (a Paragraph IV certification). Id. at § 355(j)(2)(A)(vii).

If the generic ANDA filer selects a Paragraph IV certification, it must consult the Orange Book and provide notification to each NDA or patent owner impacted by the ANDA certification “not later than [twenty] days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed.” Id. at § 355(j)(2)(B)(ii)(I). The filing of an ANDA Paragraph IV certification allows the patent holders to sue, as it is considered a technical act of infringement. The patent owners have forty-five (45) days to bring an infringement suit against the generic. If the affected patent owners do not file suit, the FDA can approve the ANDA without delay. Id. at § 355(j)(5)(B)(iii). If an affected patent owner brings an infringement suit, approval of the application is automatically stayed for thirty (30) months, or until a district court issues a final decision concluding that the patent has not been infringed or is otherwise invalid. Id.

In order to provide generic drug makers with an incentive to incur the expense and risk of a potential infringement suit by the patent holder, the first ANDA filer maintains a 180-day exclusivity period. Id. at § 355(j)(5)(B)(iv). During this period, the FDA cannot approve any other generic manufacturer’s ANDA until 180-days after the earlier of (1) the date of the first ANDA filer’s commercial marketing of its generic drug; or (2) the date of a “court [decision] that the patent is invalid or not infringed.” Id. at § 355(j)(5)(B)(iii)(I).

**E. The Patent**

The main patent protecting Cephalon's exclusivity over modafinil in the form of Provigil® is the RE'516 patent. Cephalon is the owner by assignment of the RE'516 patent, which expires on October 6, 2014. The Patent and Trademark Office (hereinafter "the PTO") issued the RE'516 patent on January 15, 2002, as a reissue patent for the 5,618,845 patent (hereinafter "'845'"), which Cephalon surrendered on that date. In December, 2002, Cephalon requested that the RE'516 patent be listed in the FDA's Orange Book. In addition to the FDA's approval of Provigil® in 1998, the FDA granted Provigil® pediatric exclusivity, as a result of studies in children, which extended the patent exclusivity to April 6, 2015. (See Apotex Second Am. Compl., ¶¶ 22, 46.)

The FDA recognized modafinil as a new chemical entity, which under the Hatch-Waxman Act, extended the original date that generic drug companies could file an ANDA to December 24, 2002.<sup>8</sup> The FDA also granted Provigil® orphan drug exclusivity because it is indicated for the treatment of a rare disease - narcolepsy. Along with the pediatric exclusivity, the orphan drug exclusivity extended the date that the FDA could approve ANDAs to June, 2006. (See Apotex Second Am. Compl., ¶¶ 41, 43, 51.)

The RE'516 patent does not cover all tablets that contain modafinil. Rather, the RE'516 patent is a formulation patent for an acetamide derivative, modafinil, having defined particle size. (See Apotex Second Am. Compl., ¶ 52.) Specifically, the RE'516 patent covers a pharmaceutical composition comprised of a "substantially homogenous mixture of modafinil particles, wherein at least 95% of the cumulative total of modafinil particles in said composition have a diameter of less

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<sup>8</sup> On that date, the four (4) Generic Defendants filed Paragraph IV certifications with respect to the RE'516 patent. (See Apotex Second Am. Compl., ¶ 51.)



than about 200 microns ( $\mu\text{m}$ ).” U.S. Patent No. RE37, 516 E col. 10 l. 49-53 (filed Apr. 1, 1999). The modafinil particles have a median diameter ranging between 2  $\mu\text{m}$  and 60  $\mu\text{m}$ . Id. at l. 54-56. The composition and effective amount is between 50 milligrams and 700 milligrams a day. Id. at l. 57-59, 65-68.

In laymen’s terms, the patent appears to cover a drug consumed orally, that is composed of at least 95% modafinil particles, which have a diameter less than 200  $\mu\text{m}$ . The drug can contain between 50 and 700 milligrams of the specified modafinil particles and is designed to alter a person’s sleep state.

**F. Summary of the Settlement Agreements Between Cephalon and the Generic Defendants**

As noted above, Plaintiffs’ antitrust allegations stem from Cephalon’s four (4) settlement agreements with Teva, Ranbaxy, Mylan, and Barr. Cephalon filed the underlying patent infringement suit against all four (4) Generic Defendants on March 28, 2003, alleging that the Generic Defendants’ ANDAs for generic Provigil® infringed on Cephalon’s RE’516 patent. The Generic Defendants each asserted patent invalidity, patent unenforceability and/or non-infringement as defenses in that litigation. By February 1, 2006, Cephalon had reached settlement agreements with each of the Generic Defendants, resolving the underlying patent infringement suit.

In each of these settlements, the Generic Defendants agreed not to market their generic versions of Provigil® until a date certain in exchange for significant payments by Cephalon for various licensing agreements, supply agreements and research and development deals. The settlement agreements are substantially similar in terms of their relation to the RE’516 patent and Provigil®, but different in terms of the side-term inducements. Cephalon was expected to pay Teva, Ranbaxy and Barr up to \$136 million under these agreements and \$45 million to Mylan. (Apotex

Second Am. Compl., ¶ 136; King Second Am. Compl., ¶ 122.) Although each respective agreement has many terms, the pertinent portions of each are discussed below.

Teva settled with Cephalon on December 8, 2005, agreeing that until April 6, 2012, Teva will:

not make, use, offer to sell, or sell or actively induce or assist any other entity to make, use, offer to sell, or sell any finished pharmaceutical product containing modafinil that is manufactured and sold pursuant to (a) NDA 20-717 and all of its current and future supplements, or (b) an ANDA for which the reference listed drug is (i) Provigil, (ii) any other product that is the subject of NDA 20-717 and all of its current and future supplements, or (iii) any other finished pharmaceutical products that contain the compound modafinil, including, without limitation, its salts, esters, enantiomers, isomers and polymorphs, including without limitation, Provigil, Sparlon, and Nuvigil, sold by Cephalon, its Affiliates, distributors and resellers that is the subject of an NDA or supplemental NDA filed or held by Cephalon for which the RE'516 Patent is listed in the Orange Book . . . .

(Teva Agreement, ¶ 2.1 with definitions.) In turn, Cephalon paid Teva tens of millions of dollars for licenses to Teva's worldwide intellectual property relating to the manufacture, development and formulation of modafinil. (Teva Agreement, ¶ 2.2(a).) Teva also agreed to manufacture and supply modafinil to Cephalon at a fixed price. (Teva Agreement, ¶ 2.4.)

Ranbaxy settled with Cephalon on December 22, 2005, agreeing that until April 6, 2012, Ranbaxy will:

not make, use, offer to sell, or sell, or actively induce or assist any other entity to make, use, offer to sell, or sell any product that is the subject of ANDA No. 76-595, or the subject of an ANDA filed or held by Ranbaxy or its Affiliates for which the reference listed drug is Provigil, within the United States, or to import or cause to be imported any product that is the subject of ANDA No. 76-595, or the subject of an ANDA filed or held by Ranbaxy or its Affiliates for which the reference listed drug is Provigil, into the United States, except as otherwise permitted under, and according to the terms of, the license granted by Cephalon in this Agreement . . . .

(Ranbaxy Agreement, ¶ 2.1 with definitions.) Ranbaxy then agreed to supply modafinil to Cephalon at a fixed price and gave Cephalon licenses to intellectual property rights related to modafinil.

(Ranbaxy Agreement, ¶¶ 2.3, 2.5.)

Mylan entered into a settlement agreement with Cephalon on January 9, 2006, agreeing that until April 6, 2012, Mylan will:

not make, use, offer to sell, or sell, or actively induce or assist any other entity to make, use, offer to sell, or sell any product that is the subject of the ANDA No. 76-594, or the subject of an ANDA filed or held by Mylan or its Affiliates for which the reference listed drug is (i) Provigil, (ii) any other product that is the subject of NDA 20-717 and all of its current and future supplements (provided that the RE'516 Patent has not been de-listed), or (iii) any other product that is the subject of an NDA or supplemental NDA filed or held by Cephalon for which the RE'516 Patent is listed in the Orange Book (provided that the RE'516 Patent has not been de-listed), within the United States, or to import or cause to be imported any product that is the subject of the ANDA No. 76-594, or the subject of an ANDA filed or held by Mylan or its Affiliates for which the reference listed drug is (i) Provigil, (ii) any other product that is the subject of NDA 20-717 and all of its current and future supplements (provided that the RE'516 Patent has not been de-listed), or (iii) any other product that is the subject of an NDA or supplemental NDA filed or held by Cephalon for which the RE'516 Patent is listed in the Orange Book (provided that the RE'516 Patent has not been de-listed), into the United States, except as otherwise permitted under, and according to the terms of, the license granted by Cephalon in this Agreement . . . .

(Mylan Agreement, ¶ 2.1 with definitions.) Cephalon and Mylan also entered into a production development collaboration agreement on January 9, 2006, for other unrelated products, under which Cephalon has paid Mylan \$45 million. (King Second Am. Compl., ¶ 122.)

Barr settled with Cephalon on February 1, 2006, agreeing:

that the RE'516 would be infringed by making, using, offering to sell, or selling any product that is the subject of the ANDA No. 76-597, or the subject of an ANDA filed or held by Barr or its Affiliates for which the reference listed drug is Provigil (the commercial formulation of modafinil developed, manufactured and, as of the date of this Agreement, sold by Cephalon pursuant to FDA approval of Cephalon's NDA 20-717) by Barr and/or its Affiliates within the United States, or by importing or causing to be imported any product that is the subject of the ANDA No. 76-597, or the subject of an ANDA filed or held by Barr or its Affiliates for which the reference listed drug is Provigil (the commercial formulation of modafinil developed, manufactured and, as of the date of this Agreement, sold by Cephalon pursuant to FDA approval of Cephalon's NDA 20-717) by Barr and/or its Affiliates into the United States, without a license to do so . . . .

(Barr Agreement, ¶ 3.1 with definitions.) Barr also agreed that until April 6, 2012:

it will not sell (a) any modafinil product that is manufactured or sold pursuant to an ANDA for which the reference listed drug is Provigil, or (b) any generic version of Cephalon's Provigil product manufactured pursuant to NDA 20-717, in the United States prior to the effective date of the license granted by Cephalon to Barr pursuant to the terms of the Modafinil License and Supply Agreement . . . .

(Barr Agreement, ¶ 3.2 with definitions.) Cephalon agreed to buy modafinil from Barr through a supply agreement and Barr gave Cephalon licenses to the Ahmed Application. (Barr Agreement, ¶¶ 3.4, 3.5.)

**G. Summary of Arguments Raised in Defendants' Motions to Dismiss**

With the exception of counts I and II of The Apotex Litigation (which relate to the declaratory judgment action on the RE'516 patent), Defendants have collectively moved to dismiss the complaints in their entirety. Defendants focus the bulk of their argument on the applicability of the scope of the patent test and assert that under this test, the settlement agreements do not go outside the scope of the patent because they do not include products beyond that scope and provide for generic market entry three (3) years prior to the end of the patent. Additionally, Defendants posit that the settlement agreements are pro-competitive and a natural consequence of the Hatch-Waxman Act.<sup>9</sup>

Plaintiffs have raised numerous responses. The F.T.C. in particular has urged that the Cephalon settlement agreements with the Generic Defendants be declared a per se antitrust violation. Collectively, Plaintiffs have pointed to numerous examples where the agreements go beyond the rights afforded to Cephalon under the applicable patent.

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<sup>9</sup> Defendants also moved to dismiss the complaints on other grounds such as lack of standing and other count specific arguments. (See generally, Defs.' Memo., supra n. 2.)

## **II. PRECEDENT - REVERSE PAYMENT AGREEMENTS**

### **A. General Precedent - Patent/Antitrust Cases**

Plaintiffs have brought claims under the Sherman Act alleging that Cephalon used the settlements with the Generic Defendants to exclude its horizontal competitors in violation of Section 1 of the Sherman Act. With the ultimate goal of stimulating competition and innovation, the Sherman Act provides that “every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.” 15 U.S.C. § 1. Although the statute prohibits all restraints of trade, the Supreme Court “has long recognized that Congress intended to outlaw only unreasonable restraints.” State Oil Co. v. Khan, 522 U.S. 3,10 (1997). The Sherman Act also states that a monopoly of any part of trade or commerce is illegal. 15 U.S.C. § 2.

In determining whether an alleged restraint of trade is “unreasonable,” courts generally apply either a per se rule or what is referred to as a “rule-of-reason analysis.” State Oil Co., 522 U.S. at 10. A per se analysis is applicable only where courts have previously considered the type of conduct at issue and have found that its expected effects are overwhelmingly anticompetitive. Id. In the rule-of-reason analysis, the question is whether the conduct at issue is anticompetitive “taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed and the restraint’s history, nature and effect.” Id. The rule-of-reason tests “whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.” Fed. Trade Comm’n v. Ind. Fed’n of Dentists, 476 U.S. 977 (1986) (citations omitted).

By contrast, but also with the goal of stimulating competition and innovation, patent law

grants an innovator “the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.” 35 U.S.C. § 154(a)(1)&(2); see also Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980).

### **B. Precedent - Reverse Payment Agreements**

To date, neither the Third Circuit nor any judge in this district has established a framework under which reverse payment patent settlements should be analyzed. Consequently, the applicable legal standard in this case rests in large part, upon our examination of how other courts have dealt with the issue. See Schaffer v. Prudential Ins. Co. of Am., 301 F.Supp.2d 383, 388 (E.D.Pa. 2003). While the outcomes have varied, those courts that have considered reverse payment agreements all recognize the tension that these agreements create between patent rights and antitrust principles. In focusing on the rights afforded by the granting of a patent, one (1) court has noted that:

Engrafted into patent law is the notion that a patent grant bestows “the right to exclude others from profiting by the patented invention.” Thus, the Patent Act essentially provides the patent owner “with what amounts to a permissible monopoly over the patented work.”

Schering, 402 F.3d at 1066 (citations omitted).

Other cases have stressed, however, that patent rights cannot create a monopoly beyond the scope of the patent. Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 708 (Fed. Cir. 1992) (the possession of a valid patent does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly). Thus, if the challenged activity simply serves as a device to circumvent antitrust law, then that activity is typically susceptible to an antitrust suit. Asahi Glass Co., Ltd. v. Pentech Pharms., Inc., 289 F.Supp.2d 986, 991 (N.D.Ill. 2003).

In 2003, the Sixth Circuit Court of Appeals found a reverse payment settlement to be a per se illegal restraint of trade in violation of the Sherman Act. Subsequently, however, the Second,

Eleventh, and Federal Circuits have taken a different approach and have adopted what is referred to as the “scope of the patent test.”<sup>10</sup> In determining which framework to apply to this case, we first briefly review this precedent and its rationale.

**1. Sixth Circuit - In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003).**

The dispute in Cardizem arose after the generic manufacturer, Andrx, filed an ANDA with a Paragraph IV certification for a generic version of the drug Cardizem. Id. at 902. Because Andrx was the first generic filer, it obtained the 180-day market exclusivity rights. Id. The manufacturer responded by filing a patent infringement suit and, thereafter, the FDA conditionally approved Andrx’s ANDA application, pending the outcome of the infringement litigation. Id.

The manufacturer and Andrx subsequently entered into an agreement that provided quarterly payments of \$10 million to Andrx. Id. In exchange, Andrx agreed not to market a generic version of Cardizem until the earliest of the following occurred: (1) there was a final, unappealable decision in the patent infringement case allowing Andrx to market the drug; (2) the manufacturer and Andrx entered into a licensing agreement; or (3) the manufacturer entered into a licensing agreement for generic Cardizem with a third party. Id. at 903. Andrx also agreed to not “relinquish or otherwise

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<sup>10</sup> See also In re K-Dur Antitrust Litig., 2009 WL 508869 (D.N.J. Feb. 6, 2009). This opinion, authored by a special master in the District of New Jersey, undertakes a comprehensive review of precedent regarding reverse payment settlements and also adopts the “scope of the patent” standard.

compromise” its 180-day period of exclusivity.<sup>11</sup> Id. at 902.

The case was reviewed by the Sixth Circuit after the district court granted the plaintiffs’ motion for partial summary judgment. Id. at 899-900. The Sixth Circuit held that the settlement agreements were per se illegal as classic horizontal and anticompetitive agreements. Id. at 908. In so ruling, the Sixth Circuit was particularly troubled by the bottleneck effect created by Andrx’s agreement not to relinquish its 180-day market exclusivity rights. Id. at 907-08. Because no other competitor could enter the market for the generic drug, the court reasoned that:

There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade.

Id. at 908.

**2. Eleventh Circuit - Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003).**

Several months after Cardizem was decided, the Eleventh Circuit reversed a district court’s per se antitrust application and grant of summary judgment for the plaintiffs in a case which was factually similar to Cardizem. Id. at 1295. The Valley Drug case involved two (2) separate settlement agreements entered into within one (1) day of each other, whereby the manufacturer agreed to pay generic companies in exchange for the generic companies’ agreements to refrain from selling the generic drug until the expiration of the applicable patents and to refrain from transferring

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<sup>11</sup> The agreement in Cardizem is unique because it delayed the generic manufacturer’s entry into the market, but did not terminate the patent infringement suit. Id. at 902. Rather, the quarterly payments were designed to delay entry by the generic manufacturer from the expiration of the thirty (30) month waiting period (or earlier if a district court ruled against the patent) until the resolution of the patent infringement case by the Supreme Court of the United States, either by denying certiorari or hearing the case. Id.



their respective 180-day market exclusivity rights as first-filers. Id. at 1300. The district court found the agreements to be per se violations of the Sherman Act, because they were “part of a larger scheme to restrain the domestic sale of generic terazosin hydrochloride.” In re Terazosin Antitrust Litig., 164 F.Supp.2d 1340, 1353 (S.D. Fla. 2000). In reversing and remanding, the Eleventh Circuit held that while reverse payment agreements may be viewed as a restraint on competition, they also constitute an enforcement of the exclusivity rights held by the patent holder. Valley Drug, 344 F.3d at 1305-06. Focusing on the lawful rights of the patent holder, the court applied a threshold analysis to determine if the anticompetitive effects of the agreements were within the scope of the patent protection. Id.

In remanding, the Eleventh Circuit instructed the district court to consider the plaintiffs’ challenge that the agreements prohibited the marketing of “any” generic terazosin and the generic’s agreement not to waive its 180-day exclusivity. Id. at 1311-12. The court stressed that these issues “require consideration of the scope of the exclusionary potential of the patent, the extent to which these provisions of the [a]greements exceed the scope, and the anticompetitive effects thereof.” Id. at 1312. The court concluded that any provision of the agreements that went beyond the exclusionary effects of the patent “may be subject to traditional antitrust analysis.” Id.

### **3. Eleventh Circuit - Schering-Plough Corp. v. Fed. Trade Comm’n, 402 F.3d 1056 (11th Cir. 2005).**

The Eleventh Circuit further clarified the standard set forth in Valley Drug when it reversed the F.T.C.’s determination that Schering had entered into illegal reverse payment agreements. Id. at 1065-66. The court emphasized that because of the inherent anticompetitive rights accompanying a patent, “an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such

exclusionary effects” is required. Id. (quoting Valley Drug, 344 F.3d at 1311, n. 27).

The court reiterated that the threshold question was the extent to which the agreements exceeded the scope of the exclusionary potential of the patent and that a finding that the agreements did so would implicate an antitrust analysis. Id. at 1066. Because the agreements at issue allowed for the generic company to enter the market years prior to the expiration of the patent, and no other products were delayed by the agreements, the court found that such agreements were within the exclusionary scope of the patent. Id. at 1068-73.

Notably, the Eleventh Circuit’s review encompassed the entire record and decision of the F.T.C. after a full hearing before an administrative law judge, which included numerous witnesses and exhibits. Id. at 1061. This is an entirely different procedural posture than the cases that are before us.

**4. Second Circuit - In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006).**

Tamoxifen continued the trend towards an analytical framework that examined whether the settlement agreement in question exceeded the scope of the patent. The Second Circuit upheld the district court’s granting of the brand name manufacturer’s motion to dismiss, reasoning that absent evidence of fraud or sham litigation, “there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.” Id. at 213. It is important to note that this is the only circuit case we are aware of involving a reverse payment settlement where the lawsuit was dismissed at the pleadings stage rather than on a motion for summary judgment.

The underlying agreements in Tamoxifen were entered into after the generic company obtained an order declaring the name brand manufacturer’s patent invalid. Id. at 194. While that

ruling was pending on appeal, the parties entered into an agreement whereby \$61 million was paid to the generic in return for their promise to not market the drug at issue, tamoxifen, until the expiration of the patent in 2002. Id. In upholding the district court's dismissal of the plaintiffs' claims, the Second Circuit concluded that while at first blush the reverse payments may seem suspicious, "suspicion abates upon reflection." Id. at 208. The court joined the Eleventh Circuit in holding that the mere fact that "a brand name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law unless the exclusionary effects of the agreement exceed the scope of the patents protection." Id. at 212. The court also focused on the benefits of settlement and emphasized the court's "longstanding adherence to the principle that 'courts are bound to encourage' the settlement of litigation." Id. at 202 (citing Gambale v. Deutsche Bank AG, 377 F.3d 133, 143 (2d Cir. 2004)).

**5. Federal Circuit - In re Ciproflaxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008).**

In Cipro there were four (4) agreements at issue: three (3) settlement agreements between Bayer, the name brand manufacturer and three (3) generic drug manufacturers in similar patent infringement suits, and one (1) supply agreement. Id. at 1328. The first three (3) agreements provided that the generic manufacturers would not challenge the validity of Bayer's patent covering the drug at issue, Cipro®, in exchange for payment by Bayer. Id. at 1328-29. Under the fourth agreement, the "Cipro Supply Agreement," Bayer agreed to supply one (1) of the generics with Cipro® for resale or, alternatively, make quarterly payments to the generic until six (6) months before the expiration of the patent. Id. Subsequent to the agreements, but prior to the filing of the antitrust suit, Bayer successfully defended its patent in a bench trial. Bayer AG v. Schein Pharm., Inc., 129 F.Supp.2d 705 (D.N.J. 2001). None of the agreements under review implicated the 180-day

exclusivity period because the generic manufacturers converted their ANDA filings to Paragraph III certifications under the settlement agreements. Cipro, 544 F.3d at 1329.

The Federal Circuit cited with approval to both the Eleventh and Second Circuits' analysis of reverse payments and applied a rule-of-reason analysis in affirming the district court's grant of the defendants' motion for summary judgment. In so doing, the Federal Circuit found it unnecessary to go beyond the first step of the rule-of-reason analysis because it found no anticompetitive effects beyond the exclusionary zone of the patent. Id. at 1335-36. Further, the court found no evidence of fraud on the PTO or sham litigation, and no manipulation of the 180-day exclusivity period. Id. at 1336. However, the Federal Circuit left open the possibility that any of those three (3) factors, if present, may result in anticompetitive effects outside of the exclusionary zone of the patent. Id. at 1333.

### **III. APPLICABLE FRAMEWORK**

#### **A. The Scope of the Patent Framework Applies**

After careful consideration, we will apply a framework which examines whether any of the agreements in question exceed the exclusionary patent rights granted to Cephalon. We do so for several reasons.

First, a reflexive conclusion that the agreements in question are per se antitrust violations, as urged by Plaintiffs, and in particular the F.T.C., ignores the "exclusionary" patent rights afforded to Cephalon. Simply stated, a patent grants its owner the lawful right to exclude others. See 35 U.S.C. §§ 271(a) (defining infringement) & 283 (providing injunctive relief for infringement); Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). As the

Eleventh Circuit explained in the Valley Drug case:

This exclusionary right is granted to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions . . . [A] patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself, or grant exclusive territorial licenses carving up the United States among its licensees. Within reason, patentees can also subdivide markets in ways other than territorial, such as by customer class . . . .

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[A] patentee's allocation of territories is not always the kind of territorial market allocation that triggers antitrust liability and this is so because the patent gives its owner a lawful exclusionary right.

Valley Drug, 344 F.3d at 1304-05 (citations omitted). Put another way in Asahi Glass, "in a reverse-payment case, the settlement leaves the competitive situation unchanged from before the [d]efendant tried to enter the market." Asahi Glass, 289 F.Supp.2d at 994.

Adopting the scope of the patent framework takes into account the patent principles noted above. At the same time, to the extent that the agreements in question improperly afford more rights than those granted under the patent, antitrust principles may apply. This approach appears to strike the proper balance between competing patent and antitrust principles.

Second, adopting the scope of the patent framework does not preclude resolution of Plaintiffs' claims that the patent in question was procured by fraud. Indeed, several Plaintiffs have asserted that Cephalon misrepresented material facts regarding its clinical trials to the PTO and that the Generic Defendants were aware of these facts when they entered into the settlement agreements with Cephalon. (King Second Am. Compl., ¶¶ 62, 73-81; Rite Aid Compl., ¶¶ 50-51, 61-68, 70; Walgreen Compl., ¶¶ 52-53, 62-72; Vista Am. Compl., ¶¶ 63, 65, 72-78; Avmed Am. Compl., ¶¶ 52, 54, 64-70; Apotex Second Am. Compl., ¶¶ 17, 21-37, 68-69, 71; F.T.C. Am. Compl., ¶¶ 44-46.)

Applying the scope of the patent framework allows exploration of these allegations.

Third, applying a rule that the reverse payment agreements in this case are per se anticompetitive would tend to ignore the long standing preference under the law favoring settlements. Several circuit courts have emphasized that while analyzing the rights protected by patent and antitrust principles, it is important to consider the general principles favoring settlement of litigation. This consideration also extends to the settlement of patent infringement suits. See Tamoxifen, 466 F.3d at 212 (settlement of patent litigation encouraged for a variety of reasons even if it leads to the survival of monopolies created by what would otherwise be weak patents); Cipro, 544 F.3d at 1333 (there is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation); Asahi Glass, 289 F.Supp.2d at 994 (“If any settlement agreement is thus to be classified as involving a forbidden ‘reverse payment’ we shall have no more patent settlements.”).

Finally, and as extensively detailed by the Second Circuit in Tamoxifen, reverse payment settlements seem to be a natural consequence of the Hatch-Waxman Act. Schering, 402 F.3d at 1074. Prior to this Act, generic drug manufacturers had to run the risk of entering the market, subjecting themselves to a finding of infringement which would forever preclude them from selling the infringing product, loss of investment revenue, and possible payment of damages to the brand name manufacturer. However, under Hatch-Waxman, the patent holder typically brings suit after the Paragraph IV ANDA filing but before marketing revenues are expended and before the generic exposes itself to possible infringement damages. This framework significantly reduces the risks involved in challenging a patent held by a brand name manufacturer. Settlements of these patent suits seem to be a logical progression of the Hatch-Waxman regulatory framework. We agree with

the Eleventh Circuit's reasoning that imposing a per se prohibition on reverse payment settlements would reduce a generic manufacturer's incentive to challenge patents. Id.; Asahi Glass, 289 F.Supp.2d at 994.

#### **IV. LEGAL ANALYSIS - MOTION TO DISMISS**

##### **A. Dismissal Under Federal Rule of Civil Procedure 12(b)(6)**

With the applicable legal framework decided, we now turn to the pending motions to dismiss. A motion to dismiss under FED. R. CIV. P. 12(b)(6) for failure to state a claim upon which relief can be granted examines the legal sufficiency of the complaint. Conley v. Gibson, 355 U.S. 41, 45-46 (1957). FED. R. CIV. P. 8(a)(2) requires that a pleading contain a "short and plain statement of the claim showing that the pleader is entitled to relief." According to the Supreme Court, the Rule 8 pleading standard "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). The Iqbal Court recently summarized the pleading standard established in Twombly:

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Iqbal, 129 S.Ct. at 1949 (citations omitted).

The Iqbal Court articulated two (2) principles that underlie Twombly's holding. First, a court must accept as true all of the factual allegations made in a pleading, but not the legal conclusions.

Id. Second, only a complaint that states a “plausible claim for relief survives a motion to dismiss.” Id. at 1950. Determining plausibility is a “context specific task.” Id. In short, “where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-but it has not shown-that the pleader is entitled to relief.” Id. (citations omitted). The Third Circuit has found that in light of Twombly, it is no longer sufficient to make an unsupported statement asserting an entitlement to relief; instead a complaint must state a claim and the grounds supporting the claim. Phillips v. County of Allegheny, 515 F.3d 224, 233-34 (3d Cir. 2008) (citing Twombly, 127 S.Ct. at 563 n. 8).

### **B. Allegations in the Complaints**

Among the four (4) groups of cases, there are seven (7) complaints before the Court.<sup>12</sup> The complaints are lengthy, some in excess of three hundred (300) paragraphs. They generally allege that the settlement agreements between Cephalon and the Generic Defendants are per se antitrust violations. In the alternative, the complaints also assert that the settlement agreements create antitrust liability because they go beyond the scope of the RE‘516 patent. In summary, the complaints allege that the agreements exceed the patent’s exclusionary authority in four (4) different ways: (1) the RE‘516 patent was invalid, unenforceable, and/or non-infringed; (2) the Generic Defendants agreement not to relinquish their 180-day exclusivity period creates a bottleneck preventing other generic entry, a right not conferred through Cephalon’s patent; (3) the individual

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<sup>12</sup> Specifically, there is one (1) complaint from each of the class Plaintiffs, opt-out Plaintiffs Rite-Aid and related Plaintiffs, and opt-out Plaintiffs Walgreen and related Plaintiffs in The King Drug Direct Purchaser Class Action; one (1) complaint each from the class Plaintiffs and opt-out Plaintiff Avmed in The Vista Healthplan End Payor Class Action; one (1) in The Apotex Litigation; and one (1) in The F.T.C. Litigation.



settlement agreements were part of a larger antitrust conspiracy; and (4) the settlement agreements prevent the sale of generic equivalents of Provigil® that were not at issue in the underlying litigation. The specific allegations set forth in the complaints are summarized as follows:

**1. The RE‘516 Patent was Invalid, Unenforceable and/or Non-Infringed**

Plaintiffs first pled that the settlement agreements exceeded the scope of the RE‘516 patent because Cephalon knew prior to the underlying patent litigation that the patent was invalid, unenforceable and/or not infringed by the Generic Defendants’ proffered products.

Specifically, the complaints assert that Cephalon knew the patent was invalid and/or unenforceable, and, therefore, any settlement agreements based on that patent were outside its scope, because the patent at issue had no scope and Cephalon’s knowledge of that fact rendered the patent litigation a “sham.” (Apotex Second Am. Compl., ¶¶ 65-67.) Plaintiffs base these allegations on the following facts:

- Cephalon violated a duty of candor to the PTO, in that the modafinil compositions and methods were developed by a French company, Laboratoire L. Lafon, and not by Cephalon, which renders the RE‘516 patent, as the reissue patent for the ‘845 patent, invalid or unenforceable;
- Cephalon bought modafinil from Lafon prior to its patent filing, which could make the patent invalid under the on-sale bar pursuant to 35 U.S.C. § 102(b); and
- Cephalon misrepresented material facts regarding its clinical trials to the PTO.

Plaintiffs allege that the Generic Defendants were aware of the above facts when they entered into the settlement agreements with Cephalon, because the Generic Defendants raised many of the same arguments in their answers and dispositive motions filed in the underlying litigation. Thus, Plaintiffs conclude that the settlement agreements on an invalid and/or unenforceable patent fall outside the

scope of the patent, because a patent's scope is bound by its validity and enforceability. (King Second Am. Compl., ¶¶ 62, 73-81; Rite Aid Compl., ¶¶ 50-51, 61-68, 70; Walgreen Compl., ¶¶ 52-53, 62-72; Vista Am. Compl., ¶¶ 63, 65, 72-78; Avmed Am. Compl., ¶¶ 52, 54, 64-70; Apotex Second Am. Compl., ¶¶ 17, 21-37, 68-69, 71; F.T.C. Am. Compl., ¶¶ 44-46.)

The complaints also allege that if the patent was not infringed by the proposed generic products, then any settlement based on infringement is outside the scope of the patent. In opposition to Defendants' motions to dismiss, Plaintiffs focus on the fact that the RE'516 patent is a narrow formulation patent for modafinil, not a patent on modafinil itself. They assert that the patent for the compound modafinil was issued in 1979 and expired in 2001, and point out that the Generic Defendants' proposed generic products did not infringe on the RE'516 patent as stated in their ANDA's for generic Provigil® filed on December 24, 2002, because the generic products had different compositions and/or particle sizes of modafinil. Thus, according to Plaintiffs, if the proposed generic products did not infringe on the RE'516 patent, then settlement agreements based on the infringement of that patent are outside the scope of the patent. (King Second Am. Compl., ¶¶ 59-60, 65, 67-70; Rite Aid Compl., ¶¶ 48, 52-53, 55-58; Walgreen Compl., ¶¶ 50, 54-55, 57-60; Vista Am. Compl., ¶¶ 66-69; Avmed Am. Compl., ¶¶ 46, 50, 56, 58-61; Apotex Second Am. Compl., ¶¶ 46, 72; F.T.C. Am. Compl., ¶¶ 34, 38-39.)

In summary, Plaintiffs claim that the underlying litigation was nothing more than "sham" litigation, and that the settlement agreements based on the patent exceeded its scope. The complaints allege that if Cephalon knew its patent was invalid and/or not infringed, then the underlying patent litigation, and subsequent settlement, exceeded the exclusionary power of Cephalon's patent. Thus, Plaintiffs assert that Cephalon entered into the settlement agreements to obtain protection from

competition precisely because they knew they could not have won an injunction preventing generic competition from a patent court. Therefore, Plaintiffs explain, Cephalon obtained “relief” above and beyond what it could have obtained from a patent court on the RE‘516 patent, and thus, the settlement agreements affording Cephalon market security were outside the scope of the patent. (King Second Am. Compl., ¶¶ 83-88, 93; Rite Aid Compl., ¶¶ 6, 69, 71, 80, 101; Walgreen Compl., ¶¶ 6, 71, 73, 82, 103; Vista Am. Compl., ¶¶ 5, 71, 79-81, 83, 88, 107; Avmed Am. Compl., ¶¶ 6, 55-56, 63, 71-75, 80, 85, 104; Apotex Second Am. Compl., ¶¶ 70-79; F.T.C. Am. Compl., ¶ 47.)

## **2. The Settlements Created a Bottleneck**

The second theory pled by Plaintiffs as to how the settlement agreements fall outside the scope of the patent, is that the agreements created a bottleneck preventing entry into the market by other generic companies, such as Apotex. Under the Hatch-Waxman Act, the first ANDA filers, are awarded 180-days of market exclusivity after the RE‘516 patent expires or is declared invalid, unenforceable and/or not infringed. Thus, Plaintiffs explain that if the 180-day period of exclusivity is never triggered for the first-filers - here, the Generic Defendants, then all subsequent generic companies such as Apotex will be blocked from the market. Plaintiffs posit that the settlement agreements included provisions in which the Generic Defendants agreed not to give up their 180-day exclusivity, thus preventing other generic companies from entering the market. Plaintiffs’ complaints point out that even if the settlement agreements do not explicitly require the Generic Defendants to maintain their 180-day exclusivity, then there were secondary agreements between all of the companies who agreed not to relinquish their first-filer exclusivity. Plaintiffs contend that such agreements are outside the scope of the patent because they extended Cephalon’s right to market exclusivity by preventing generic entry beyond that which Cephalon would ordinarily be

entitled to by the patent itself. (King Second Am. Compl., ¶¶ 49, 51, 56, 108-09, 116, 120, 124, 128, 131-37; Rite Aid Compl., ¶¶ 121-24; Walgreen Compl., ¶¶ 123-26; Vista Am. Compl., ¶¶ 128-30; Avmed Am. Compl., ¶¶ 39, 57, 124-27; Apotex Second Am. Compl., ¶¶ 96, 99, 113-14, 122-24, 146, 159-60, 166, 171-72; F.T.C. Am. Compl., ¶¶ 87-90.)

### **3. The Agreements Were Part of a Larger Antitrust Conspiracy**

The third theory pled by Plaintiffs as to how the settlement agreements were outside the scope of the patent is that all of the agreements were part of an overall elaborate horizontal agreement not to compete. Plaintiffs allege that this conspiracy and the ensuing reverse settlement agreements allocated all sales of modafinil in the United States to Cephalon, prevented the sale of generic versions of Provigil® for six (6) or more years, and fixed the price of Provigil® because there is no generic competition.

In support of these allegations, Plaintiffs highlight that each agreement contained a “most favored nation clause,” which guaranteed that each of the Generic Defendants’ licensed entry date would be accelerated if any other Generic Defendant did not settle or entered early. Plaintiffs also point out that each of the agreements contain the same entry date of April 6, 2012. Thus, they assert that in order to induce any individual Generic Defendant to sign the settlement agreements, Cephalon had to induce all of the Generic Defendants to sign the agreements because no Generic Defendant would agree to stay off the market unless all its competitors did so as well. Plaintiffs also allege that agreements contain numerous side-term inducements related to intellectual property licenses, supply agreements, and co-development deals, which were not independent business transactions, but rather, were inexplicably related to the Provigil® agreements. In sum, Plaintiffs allege that all of the above amounts to anticompetitive behavior that goes well beyond the exclusivity rights Cephalon ordinarily

would have had under the patent. (King Second Am. Compl., ¶¶ 7, 85-88, 104-09, 111-28, 180-84; Rite Aid Compl., ¶¶ 5, 75, 92, 94-97, 99, 104, 108, 111, 140, 147, 154, 161, 168; Walgreen Compl., ¶¶ 5, 77, 94, 96-99, 101, 106, 110, 113, 142, 149, 156, 163, 170; Vista Am. Compl., ¶¶ 4, 97-99, 102-06, 111, 114-15, 118, 121, 123, 152; Avmed Am. Compl., ¶¶ 5, 79, 96, 98-99, 101-03, 107, 109-11, 113, 115-16, 118, 145; Apotex Second Am. Compl., ¶¶ 97, 99, 104, 106, 125-27, 133-40, 146, 168-70; F.T.C. Am. Compl., ¶¶ 58-60, 62-64, 66-69, 71-72, 74-77.)

#### **4. The Agreements Prohibit the Sale of Other Products in Addition to Generic Equivalents of Provigil**

The fourth theory pled by Plaintiffs as to how the settlement agreements extended beyond the scope of the patent is that the language of the agreements themselves prohibit the sale of products other than generic equivalents of Provigil®. For instance, Plaintiffs alleged that the Teva and Mylan agreements prohibit the sale of all generic Provigil® and generic equivalents of successor products, not just the generic Provigil® equivalent at issue in the underlying litigation. As the Direct Purchasers point out in their responses to the Court's follow-up questions to counsel, the Teva agreement "provides that Teva will not sell 'Subject Modafinil Products - defined in ¶ 1.19 to include any generic version of Provigil, any generic versions of drugs that may be subject to future supplements . . . and any other Cephalon modafinil products.'" (Direct Purchasers' Resp. to Ct.'s Questions, p. 3.) Plaintiffs also claimed that the Ranbaxy and Barr settlement agreements prohibit the sale of not only the generic Provigil® at issue in the underlying litigation, but also any other generic versions of Provigil®, which is also outside the scope of the patent. (King Second Am. Compl., ¶¶ 108, 116, 120, 124; Rite Aid Compl., ¶¶ 96, 104, 108, 111; Walgreen Compl., ¶¶ 98, 106, 110, 113; Apotex Second Am. Compl., ¶ 147; F.T.C. Am. Compl., ¶¶ 79-81.)

**C. Under the Scope of the Patent Test Plaintiffs Have Pled a Plausible Cause of Action**

Having determined that the scope of the patent test framework applies, and viewing the complaints and the allegations contained therein in the light most favorable to Plaintiffs, we find that sufficient facts have been alleged to establish that the agreements in question grant greater rights than those conferred under the patent. As detailed above, the complaints allege fraud and misrepresentations to the PTO, non-infringement, patent invalidity, “sham litigation,” the creation of a bottleneck, antitrust conspiracy and agreements between Cephalon and the Generic Defendants regarding products not protected by Cephalon’s patent. Indeed, some of the terms of the agreements referenced in the complaints contemplate “future supplements” and “any other Cephalon Modafinil Products.”

To the extent that a factual basis exists on any of these theories, Plaintiffs may be able to prevail under the scope of the patent test and move forward with their antitrust claims. Indeed, Cephalon seems to acknowledge, at least as it pertains to the issue of “side-term inducements,” that a factual dispute may exist. In their motions to dismiss, Cephalon argues that the “record” will support that these “side-term inducements” were in fact “legitimate business arrangements for which fair consideration was paid.” (Cephalon Memo., p. 8. (doc. no. 200 in 2:06-cv-1797).) The record in this case has not, however, been developed. If in fact, Cephalon and the Generic Defendants did have “side-term inducements,” a fact we must accept as true at this stage of the case, those facts could sustain Plaintiffs’ antitrust claims. Consequently, plausible antitrust allegations have been pled.

The reasoning of several cases previously discussed supports our conclusion that Defendants' request to have the case dismissed at this stage should be rejected. For instance, in Valley Drug, in reversing the district court's determination that the settlement agreements were per se illegal, the Eleventh Circuit noted that on remand the district court should consider the allegations raised by plaintiffs that the agreements went beyond the scope of the patent. Valley Drug, 344 F.3d at 1312-13. Plaintiffs' allegations included claims that the agreements exceeded the scope of the patent due to the fact that they: (1) prohibited marketing of non-infringing products; (2) prohibited marketing of non-infringing products beyond a court's declaration of invalidity of the patents; and (3) prohibited the generic companies from waiving the 180-day exclusivity period. Id. at 1306 n. 18. The court stressed that, "these prohibitions may be beyond the scope of Abbott's lawful right to exclude, and, if so, would expose appellants to antitrust liability for any actual exclusionary effects resulting from these provisions that appellees can prove at the causation and damages stages of litigation." Id. The court also noted that the plaintiffs' allegations that the litigation that led to the settlement was a "sham" should also be considered by the district court. Id. at 1306.

On remand, the district court did in fact conclude that the agreements exceeded the scope of the patent. The court reached this conclusion as the agreement by the generic companies to refrain from entering the market until there was a final, non-appealable judgment of invalidity against the patent, exceeded the exclusionary power of that patent because similar protection could not have been obtained by enforcing the patent through litigation. In re Terazosin Hydrochloride Antitrust Litig., 352 F.Supp.2d 1279, 1307-08 (S.D.Fla. 2005).

Many of the same claims that were raised in Valley Drug that eventually led to a finding in favor of the plaintiffs are also pressed by Plaintiffs in this case. For instance, Plaintiffs allege that

the agreements cover all generic modafinil products and include products not covered by any of Cephalon's patents. (King Second Am. Compl., ¶¶ 108, 116, 120, 124; Rite Aid Compl., ¶¶ 96, 104, 108, 111; Walgreen Compl., ¶¶ 98, 106, 110, 113; Apotex Second Am. Compl., ¶ 147; F.T.C. Am. Compl., ¶¶ 79-81.) The Eleventh Circuit explicitly recognized that such agreements could expose the brand name manufacturer to antitrust liability. Valley Drug, 344 F.3d at 1312 ("Any provisions of the [a]greements found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis."). Further, Plaintiffs allege that Cephalon knew their patent was invalid from the beginning, and therefore any agreement exceeds the scope of the patent, because an invalid patent has no scope. (King Second Am. Compl., ¶¶ 62, 73-81; Rite Aid Compl., ¶¶ 50-51, 61-68, 70; Walgreen Compl., ¶¶ 52-53, 62-72; Vista Am. Compl., ¶¶ 63, 65, 72-78; Avmed Am. Compl., ¶¶ 52, 54, 64-70; Apotex Second Am. Compl., ¶¶ 17, 21-37, 68-69, 71; F.T.C. Am. Compl., ¶¶ 44-46.) While the Eleventh Circuit did not address the validity of this argument, they did state that "many lower courts" recognize that these claims are valid under antitrust law. Valley Drug, 344 F.3d at 1309.

In Schering, the Eleventh Circuit vacated a F.T.C. determination that reverse settlement agreements violate Section 1 of the Sherman Act. Schering, 402 F.3d at 1066-68. In reversing the F.T.C. and reiterating that "the scope of the exclusionary potential of the patent" must be considered, the court noted that the plaintiffs had not raised allegations that the patent itself was invalid or that the resulting infringement suits were "shams." Id. Here, unlike Schering, Plaintiffs have alleged that the patent is invalid and that Cephalon committed a fraud on the PTO. (King Second Am. Compl., ¶¶ 62, 73-81; Rite Aid Compl., ¶¶ 50-51, 61-68, 70; Walgreen Compl., ¶¶ 52-53, 62-72; Vista Am. Compl., ¶¶ 63, 65, 72-78; Avmed Am. Compl., ¶¶ 52, 54, 64-70; Apotex Second Am. Compl., ¶¶



17, 21-37, 68-69, 71; F.T.C. Am. Compl., ¶¶ 44-46.) Moreover, at this stage of the litigation, wherein we are examining the complaints, we must accept as true Plaintiffs' contentions that the agreements were drafted as broadly as possible, affording Cephalon greater exclusionary rights than they may be entitled to under the patent. This is far different than the conclusions reached in Schering where the court found that the agreements in question "demonstrate an efficient narrowness," and did so after review of a comprehensive administrative court hearing. Schering, 402 F.3d at 1073.

In Tamoxifen, the court, in validating a reverse payment agreement, noted that "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it presumably entitled: a lawful monopoly." Tamoxifen, 466 F.3d at 208-09. In the case before us, Plaintiffs have alleged sham litigation and, at this stage, we are obligated to view this allegation in a favorable light and allow discovery to proceed. (King Second Am. Compl., ¶¶ 83-88, 93; Rite Aid Compl., ¶¶ 6, 69, 71, 80, 101; Walgreen Compl., ¶¶ 6, 71, 73, 82, 103; Vista Am. Compl., ¶¶ 5, 71, 79-81, 83, 88, 107; Avmed Am. Compl., ¶¶ 6, 55-56, 63, 71-75, 80, 85, 104; Apotex Second Am. Compl., ¶ 79; F.T.C. Am. Compl., ¶ 47.)

Certain findings in the Federal Circuit Cipro case also support our decision to deny Defendants' motions to dismiss. There, the reverse payment agreements all required the generic companies to convert their ANDA filings to Paragraph III certifications, thereby alleviating any possible bottleneck by forfeiting any claim to 180-day exclusivity and clearing a path for other generic companies to challenge the brand name manufacturer's patent. Cipro, 544 F.3d at 1329. Here, Plaintiffs have alleged that the Generic Defendants have done just the opposite by maintaining their 180-day exclusivity with no intention of going to market. (King Second Am. Compl., ¶¶ 49,

51, 56, 108-09, 116, 120, 124, 128, 131-37; Rite Aid Compl., ¶¶ 121-24; Walgreen Compl., ¶¶ 123-26; Vista Am. Compl., ¶¶ 128-30; Avmed Am. Compl., ¶¶ 39, 57, 124-27; Apotex Second Am. Compl., ¶¶ 96, 99, 113-14, 122-24, 146, 159-60, 166, 171-72; F.T.C. Am. Compl., ¶¶ 87-90.) Indeed, there is no mention in any of Defendants' memoranda filed in support of their motions to dismiss that the agreements required the Generic Defendants to convert their ANDA filings from Paragraph IV certifications to Paragraph III certifications. Moreover, unlike the claims before this Court, in Cipro, there were no allegations of fraud or inequitable conduct before the PTO. Rather, the strength of the brand name manufacturer's patent was demonstrated multiple times when it successfully defended patent infringement suits against subsequent generic ANDA Paragraph IV filers. Cipro, 544 F.3d at 1329.

We also note that all of the circuit courts, except one (1), who have adopted the scope of the patent framework and dismissed the case, did so where the litigation was at the summary judgment stage of the proceedings.<sup>13</sup> In Valley Drug, the facts were "largely uncontested by the parties," which is certainly not the case here. Valley Drug, 344 F.3d at 1298 n. 7. In Schering, the Eleventh Circuit's analysis was based upon review of an extensive administrative hearing which included numerous exhibits and witnesses, also not present here. Schering, 402 F.3d at 1061. Given the fact

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<sup>13</sup> Although the district court in Tamoxifen dismissed the complaint at the motion to dismiss phase, the facts of Tamoxifen are almost entirely different from those in the case sub judice. In re Tamoxifen Citrate Antitrust Litig., 277 F.Supp.2d 121 (E.D.N.Y. 2003). Most notably, the plaintiffs in Tamoxifen made no allegations whatsoever that the terms of the agreements went outside the scope of the patent, either by restricting the sale of additional drugs not implicated by the patent, or by virtue of fraud on the PTO by the patent-holder. Id. Rather, the Second Circuit's discussion focuses on the good-faith nature of the settlement after a district court ruling of invalidity. Tamoxifen, 466 F.3d at 204-06. Those issues are simply not present in our case.

that a Rule 16 Conference in these cases has not yet taken place, the record before us is only Plaintiffs' complaints, which must be viewed in a light favorable to Plaintiffs, and the settlement agreements.

Lastly, we have carefully considered the costs of discovery and are cognizant of the admonition that if there is "nothing suspicious about the circumstances of patent settlement," a third party should not be permitted to haul the parties to a patent settlement "over the hot coals of antitrust litigation." Asahi Glass, 289 F.Supp.2d at 992. It may ultimately be proven that the agreements in question do not confer Cephalon greater exclusionary authority than the patent, and that any "suspicions" about the settlements are unfounded. Nonetheless, Plaintiffs have set forth sufficient, plausible allegations to establish the contrary.

#### **IV. STANDING**

Defendants also challenge Plaintiffs' standing to pursue antitrust claims. The following test is applicable in determining antitrust standing:

(1) the causal connection between antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages.

In re Lower Lake Erie Iron Ore Antitrust Litig., 998 F.2d 1144, 1165-66 (3d Cir. 1993). This "standing analysis is essentially a balancing test comprised of many constant and variable factors and that there is no talismanic test capable of resolving all § 4 standing problems." Brayman v. Bassett Furniture Indus., Inc., 552 F.2d 90, 99 (3d Cir. 1977).

The only argument raised by Defendants regarding standing is causation. Defendants assert that Plaintiffs' argument that "but-for" Defendants' settlement agreements a generic company would have entered the market is too speculative to satisfy the causation requirement for standing. (See, i.e., Cephalon Memo., pp.40-44 (doc. no. 200 in 2:06-cv-1797); Cephalon Memo., pp. 29-32 (doc. no. 157 in 2:06-cv-2768).) Plaintiffs respond that "but-for" Defendants' settlement agreements, companies such as the Generic Defendants and/or Apotex would have entered the market resulting in Provigil® being available in cheaper generic form. Plaintiffs' claim that the overcharges on their purchases of Provigil® and Apotex's barrier to market entry are precisely the type of injuries which directly resulted from the specific type of antitrust activity the Sherman Act was intended to prevent. (See, i.e., Direct Purchasers Memo., pp. 57-62 (doc. no. 213 in 2:06-cv-1797); Apotex Memo., pp. 20-26 (doc. no. 161 in 2:06-cv-2768).)

In the In re K-Dur Antitrust Litigation, the court extensively addressed this very issue, and, consequently, we will not engage in a protracted analysis here. In re K-Dur Antitrust Litig., 338 F.Supp.2d 517, 534-35 (D.N.J. 2004). The court found that the plaintiffs' allegations that anticompetitive agreement(s) between a name brand manufacturer and generic companies, which blocked generic entry into the market causing higher prices on the name brand pharmaceutical product, could survive a motion to dismiss premised upon lack of standing. Id. at 535. The court reasoned that it was the alleged anticompetitive agreement(s) which caused the antitrust injury, not the Hatch-Waxman Act, because the Hatch-Waxman Act was designed to promote competition

between name brand manufacturers and generic companies.<sup>14</sup> Id.

Here, the direct purchaser and end payor Plaintiffs have alleged that absent the anticompetitive settlement agreements between Cephalon and the Generic Defendants, they would have been able to purchase generic Provigil® at significantly reduced prices. (King Second Am. Compl., ¶ 8; Rite Aid Compl., ¶ 10; Walgreen Compl., ¶ 10; Vista Am. Compl., ¶ 6; Avmed Am. Compl., ¶ 8.) Therefore, the direct purchaser and end payor Plaintiffs have sufficiently pled an antitrust injury which stems from the Defendants' conduct, and accordingly, meet the pleading requirements for standing.

As to the Defendants' challenge to Apotex's standing in the antitrust context, we have previously addressed Apotex's standing to pursue a declaratory judgment action on the RE'516 and '346 patents in Apotex, Inc. v. Cephalon, Inc., 2010 WL 678104, at \* 3-6. There, we held that Apotex's injury was premised on the barrier to market entry as a result of Defendants' anticompetitive settlement agreements. The same analysis which applied in the patent declaratory judgment framework applies to Apotex's standing in the antitrust context and thus, Apotex's claims will be allowed to proceed.

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<sup>14</sup> The court distinguished the facts before it from those in City of Pittsburgh v. West Penn Power Co., 147 F.3d 256 (3d Cir. 1998), because of the distinctive designs of the applicable statutory framework. K-Dur, 338 F.Supp.2d at 535. That same analysis is applicable to the instant cases as well.

**V. ADDITIONAL ISSUES RAISED IN THE DEFENDANTS' MOTIONS TO DISMISS**

**A. Vista Healthplan Class Action - Count IV - For Compensatory and Multiple Damages Under Antitrust and/or Consumer Protection Statutes of Indirect Purchaser States and Avmed - Count II - Violation of Florida Deceptive and Unfair Trade Practices Act**

The class Plaintiffs in The Vista Healthplan End Payor Class Action have brought claims under the antitrust and/or consumer protection statutes of twenty-six (26) states, and Avmed has brought claims under the consumer protection statute of Florida. Defendants have moved to dismiss all of these claims for a litany of reasons. The end payor class Plaintiffs voluntarily withdrew their claims under the antitrust statutes of Louisiana, Massachusetts and New York, and their claims under the consumer protection statutes of Kentucky, Louisiana and Wisconsin, and consequently, the motions to dismiss will be granted regarding those claims. (Plaintiff Memo., p. 65 n. 2 (doc. no. 92 in 2:06-cv-1833).) Additionally, Defendants moved to dismiss the end payor class Plaintiffs' claims under Florida's antitrust statute, FLA. STAT. ANN. § 542.15 (West 2010), and the end payor class Plaintiffs did not respond to that portion of the motion. Therefore, the Court will consider this issue conceded and the motions to dismiss will be granted on that claim as well. The remaining issues in the motions to dismiss will be addressed in the order in which they have been raised.

Defendants first assert that all consumer protection and antitrust claims brought where none of the named Plaintiffs reside should be dismissed for lack of standing.<sup>15</sup> (See Cephalon Memo., p. 22 (doc. no. 86 in 2:06-cv-1833).) In support of their argument, Defendants rely almost entirely on In re Wellbutrin XL Antitrust Litig., 260 F.R.D. 143 (E.D.Pa. 2009). This reliance is misplaced

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<sup>15</sup> The named end payor class Plaintiffs reside in Pennsylvania and New York. (Vista Am. Compl., ¶¶ 13-17.) Avmed, an opt-out Plaintiff, resides in Florida. (Avmed Am. Compl., ¶ 16.)

because, while the court in Wellbutrin held that it was proper to determine standing prior to class certification and considered only the named plaintiffs, the court went on to find the named plaintiffs had standing in any state in which their member constituents resided. Id. at 156.

In this case, end payor class Plaintiffs have alleged that Plaintiff District Council 37 Health & Security Plan has members residing in forty-nine (49) states, while Plaintiff Pennsylvania Employees Benefit Trust Fund has over 270,000 members, residing in a number of states. (Vista Am. Compl., ¶¶ 16-17.) Therefore, Plaintiffs “have identified an injury in fact that is fairly traceable to conduct taking place in states where their members purchased” Provigil®. Wellbutrin, 260 F.R.D. at 156. The injuries “would be redressed by a favorable determination under the laws of the states where their members purchased” Provigil®. Id. Plaintiffs, therefore, have standing in forty-nine (49) states, including the twenty-six (26) named in their complaints.

Defendants next argue that all of the state law claims should be dismissed because the statutes must be construed consistently with federal antitrust law. (See Cephalon Memo., p. 25 (doc. no. 86 in 2:06-cv-1833).) Accepting arguendo that Defendants are correct in their interpretation of the state statutes, this argument must still be rejected because the federal antitrust claims are proceeding.

Defendants next argue that the claims under the Mississippi, Utah, and West Virginia antitrust statutes should be dismissed because the statutes only apply to conduct which is primarily intrastate. (See Cephalon Memo., p. 34 (doc. no. 86 in 2:06-cv-1833).) The laws of Mississippi, Utah, and West Virginia, however, do not have such a requirement. Consequently, Defendants’ argument on that point is meritless.

Under Mississippi law, Plaintiffs need “only have to plead facts that would lead to a

reasonable inference that the defendant and its co-conspirators wanted the Mississippi vendors to charge Mississippi consumers a higher price as a result of the lack of competition.” Hood ex rel. State v. BASF Corp., 2006 WL 308378, at \* 10 (Miss. Ch. Jan. 17, 2006). The allegations in Plaintiffs’ complaint clearly allege such facts. (See Vista Am. Compl., ¶¶ 147-48, 175.)

The Utah Antitrust Act has no such requirement, but instead bars all antitrust activity with regard to “trade or commerce.” The statute defines “trade or commerce” as “all economic activity involving, or relating to, any commodity, service, or business activity.” UTAH CODE ANN. § 76-10-913 (West 2010). The Defendants’ citation to a definition of “commerce” from a separate section of the Utah Code is unconvincing. (See Cephalon Memo., p. 35 (doc. no. 86 in 2:06-cv-1833).)

With regard to West Virginia, Defendant asks this Court to find that the statute is limited to intrastate commerce based on a single line from Anziulewicz v. Bluefield Cmty. Hosp., Inc., 531 F.Supp. 49, 53 (S.D. W.Va. 1981), a case discussing federal jurisdiction and the Supremacy Clause. Id. This issue has not been specifically addressed in West Virginia; however, the West Virginia antitrust statute specifically dictates that it is to be “construed liberally.” W. VA. CODE § 47-18-16 (West 2010). One (1) sentence from a case completely unrelated to the issues before this Court is insufficient to warrant a finding to the contrary.

Finally, Defendants argue that the end payor Plaintiffs have not alleged fraudulent or deceptive conduct, and, therefore, their claims under various consumer protection laws should be dismissed. (See Cephalon Memo., p. 41 (doc. no. 86 in 2:06-cv-1833).) Accepting the Plaintiffs’ claims as true, Plaintiffs have clearly alleged that Cephalon and the Generic Defendants engaged in fraudulent or deceptive conduct by entering into confidential illegal agreements with the goal of keeping the price of Provigil® artificially high. (See Vista Am. Compl., ¶¶ 97-124.) See, e.g., Cox



v. Microsoft Corp., 778 N.Y.S.2d 147, 148 (N.Y.App.Div. 2004).

**B. Vista Healthplan Class Action - Count V - Unjust Enrichment and Avmed - Count III - Unjust Enrichment**

Defendants argue that the end payor Plaintiffs' unjust enrichment claims should be dismissed because Plaintiffs cannot establish a violation of state and/or federal law. As has been previously discussed, this argument fails because Plaintiffs have pled sufficient facts to establish violations of antitrust law at this stage in the litigation. Defendants also argue that the end payor Plaintiffs' unjust enrichment claim should be dismissed as an "end-run" around statutory limitations on remedies. (Cephalon Memo., p. 47 (doc. no. 86 in 2:06-cv-1833).) Several courts, however, have found just the opposite. End payor unjust enrichment claims survived motions to dismiss in In re Terazosin Hydrochloride Antitrust Litig., 220 F.R.D. 672, 679 n. 40 (S.D.Fla. 2004), and In re Cardizem CD Antitrust Litig., 105 F.Supp.2d 618, 669-71 (E.D.Mich. 2000).<sup>16</sup> The courts also explained that unjust enrichment claims are viable regardless of the applicable state antitrust laws. Id. Furthermore, it has long been recognized that plaintiffs are allowed to plead alternative causes of action and unjust enrichment is commonly recognized as one (1) of those permissible alternative causes of action. See, e.g., Terazosin, 220 F.R.D. at 697 n. 40. Accordingly, we will not dismiss the end payors' unjust enrichment counts.

**C. Apotex - Count XII - Patent Misuse**

Cephalon has moved to dismiss Apotex's patent misuse claim but admits that "[t]he standard

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<sup>16</sup> The court in Cardizem also rejected the defendants' arguments regarding privity under New York law, and for the purposes of these motions, we will adopt the same analysis and ruling on that issue. Cardizem, 105 F.Supp.2d at 669-71.

for patent misuse mirrors the scope of the patent test for an antitrust claim - i.e., the conduct is lawful so long as it does not restrain competition to any greater extent than the underlying patents.” (Cephalon Memo., p. 33 (doc. no. 157 in 2:06-cv-2768) citing Monsanto Co. v. McFaling, 363 F.3d 1336, 1341 (Fed. Cir. 2004); and Mallinckrodt, 976 F.2d at 704.) As we have thoroughly addressed the issue of the scope of the patent test and its application to the facts as pled by all Plaintiffs, including Apotex, we will not reiterate that analysis here. Given that Apotex has sufficiently pled facts establishing that the settlement agreements could go outside the scope of the patent (see supra Section IV, subsection C), we also find that Apotex has sufficiently pled facts to survive Cephalon’s motion to dismiss the patent misuse claim.

**D. Apotex - Count XIII - Tortious Interference with a Prospective Business Relationship**

Cephalon has also moved to dismiss Apotex’s tortious interference with a prospective business relationship claim. Cephalon argues that Apotex’s claim fails because it has not identified any potential customer with whom the Defendants interfered, the settlement agreements do not restrict anything beyond the scope of the patent, and the claims cannot be based on mere speculation. (Cephalon Memo., pp. 36-38 (doc. no. 157 in 2:06-cv-2768).)

The second argument fails for the very reasons extensively addressed above. (See supra Section IV, subsection C.) As to points one (1) and three (3) of Cephalon’s argument:

it has been held in an antitrust case similar to this that the “allegation that [a name brand manufacturer] brought a sham patent infringement suit against [a generic manufacturer] with the purpose of keeping it out of the generic [drug] market [was] sufficient to state a claim for tortious interference with prospective business advantages.”

Abbott Labs. v. Teva Pharms. USA, Inc., 432 F.Supp.2d 408, 433 (D.Del. 2006) citing SmithKline

Beecham Corp. v. Apotex Corp., 383 F.Supp.2d 686, 704 (E.D.Pa. 2004). Apotex has sufficiently pled that the underlying litigation was a sham and that the sham litigation resulted in agreements which were designed to keep other generic companies, such as Apotex, off the market and interfere with their prospective business relationships. (Apotex Second Am. Compl., ¶¶ 79, 96, 99, 113-14, 122-24, 146, 159-60, 166, 171-72, 294, 296-300.) Therefore, we will not dismiss count XIII of Apotex's second amended complaint.

**E. Apotex - Striking Prayers for Relief**

Cephalon has moved to strike Apotex's prayer for relief which seeks a Court order mandating that the Generic Defendants waive their 180-day first-filer exclusivity. (Apotex Second Am. Compl., ¶ 301(i).) Cephalon suggests that this prayer for relief is not appropriate because under 21 U.S.C. § 355(j)(5)(D)(i)(V) only the F.T.C. or the Attorney General may seek such relief if they successfully challenge a violation of antitrust law. (Cephalon Memo., pp. 38-39 (doc. no. 157 in 2:06-cv-2768).) 21 U.S.C. § 355(j)(5)(D) provides several ways in which a generic company may forfeit their 180-day first-filer exclusivity, including section (i)(V) addressed above. Given the relatedness of The F.T.C. Litigation to The Apotex Litigation and the several different types of forfeiture events, the applicability of which has yet to be determined in the cases at hand, the Court will not strike Apotex's prayer for relief (i) at this point in the litigation.

Cephalon has also moved to strike Apotex's prayer for relief which seeks a Court order that "the provisions in the agreements between Cephalon and the Generic Defendants that allows for the Generic Defendants to launch generic versions of modafinil upon a third party launch of generic versions of modafinil" be stricken and that "the Generic Defendants not be allowed to enter the market prior to April, 2012." (Apotex Second Am. Compl., ¶ 301(j) & (k).) Cephalon's sole

argument for striking this prayer for relief is that the entry provision in the settlement agreements is pro-competitive, so there is no injury justifying such relief by the Court. Apotex has pled, however, that the settlement agreements are anticompetitive and for the purposes of the motions to dismiss that is controlling. (Apotex Second Am. Compl., ¶¶ 96, 117.) Therefore, the Court will not strike Apotex's prayer for relief (j) and (k).

## **VI. CONCLUSION**

For the reasons set forth above, Defendants' motions to dismiss will be denied in part and granted in part, as explained in this Opinion. Our Order follows.